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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/664,338

09/17/2003

Michael P. Dwyer

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03/31/2005

SCHERING-PLOUGH CORPORATION  
PATENT DEPARTMENT (K-6-1, 1990)  
2000 GALLOPING HILL ROAD  
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EXAMINER

HUANG, EVELYN MEI

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 03/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/664,338

Applicant(s)

DWYER ET AL.

Examiner

Evelyn Huang

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19, 29 and 31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18 and 19 is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 10-17, 29, 31 is/are rejected.
- 7) ☒ Claim(s) 5 and 7-9 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Claims 1-19, 29, 31 are pending. Claims 20-28, 30 have been canceled according to the amendment filed on 12-23-2004.

#### ***Claim Rejections - 35 USC § 112***

2. The rejection for Claims 2, 10 under 35 U.S.C. 112, second paragraph is withdrawn because the amendment has obviated the rejection.

#### ***Claim Rejections - 35 USC § 102***

3. The rejection for Claims 1, 31 under 35 U.S.C. 102(b) as being anticipated by Hand et al. (J. Org. Chem. 1978, 43(14): 2900-6, PTO-1449) is withdrawn in view of the exclusion of the prior art compound from the instant claims.
4. The rejection for Claims 1-4, 10, 12-17, 29, 31 under 35 U.S.C. 102(b) as being anticipated by Yoshino is withdrawn in view of the exclusion of Yoshino's Example 20 from the instant claims.
5. The rejection for Claims 1-4, 10-17, 29, 31 under 35 U.S.C. 102(b) as being anticipated by Yoshino (EP 673937, PTO-1449) is withdrawn in view of the exclusion of Yoshino's compounds from the instant claims.

#### ***Claim Rejections - 35 USC § 102***

6. The rejection for Claims 1-4, 6, 10, 12-17 under 35 U.S.C. 102(a) as being anticipated by Basso et al. (Tetrahedron. 2002, 58:4445-4450, published on May 27, 2002, PTO-1449) is withdrawn in view of the exclusion of Basso's compound 16 from the instant claims.

***Claim Rejections - 35 USC § 103***

7. The rejection for Claims 1-4, 6, 10-17, 29, 31 under 35 U.S.C. 103(a) as being unpatentable over Oku (5574042) is maintained for reasons of record.

Applicants argue that pharmaceutical art is highly unpredictable that a slight modification in the structure would lead to drastic changes in the biological activity, as shown in Breitenlechner et al., Capdeville et al., Hunt et al., Rewcastle et al, and Chang et al.

However, all the compounds in the above references are structurally different from the instant. In view of the high degree of unpredictability in the pharmaceutical art, as demonstrated in the references provided, one of ordinary skill in the art would not have any basis to extrapolate the results of these structurally dissimilar compounds to Oku's compounds or to the instant compounds.

Oku generically discloses a bradykinin antagonist compound (column 1), and the composition thereof, which encompasses the instant. A specific example, 3-chloro-8-(2,6-dichlorobenzylamino 2, 7-dimethyl-imidazo[1,2-a]pyridine, is described (Example 3, column 59, compound (7) ). Oku's example is the same as the instant except for only one difference: it has a 2-methyl whereas the compound of instant claim 6 has a hydrogen. The methyl is the next adjacent homolog of hydrogen. Furthermore, Oku expressly teaches that methyl and hydrogen are optional choices (column 1, lines 52-53, definition of R2). At the time of the invention, one of ordinary skill in the art would be motivated to replace the methyl with the alternative hydrogen to arrive at the instant invention with the reasonable expectation of obtaining an additional bradykinin antagonist compound since Oku had clearly taught that any species within the disclosed genus would be useful as a bradykinin antagonist. In the absence of unexpected results in a side by side comparison between the prior art compound and the inventive compound, the instant remains obvious over Oku.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 10-17, 29, 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

A description of the species compounds in the proviso in claim 1 is not found in the specification.

A generic disclosure does not satisfy the description requirement for a species within the genus. The court has held that 'disclosure such as that found in formula and words of claim does not amount to a disclosure, sufficient to support a specific claim, of every compound a skilled chemist can see within the scope of that claim; specific claims to single compounds require reasonably specific supporting disclosure;....a chemist could name all the compounds within scope of the broadest claim, which claim is supported by broad disclosure; this does not constitute support for each compound individually when separately claimed' In re Ruschig, 154 USPQ 118. See MPEP 2163.05.

The rejection is applicable to claims dependent on claim 1.

### *Conclusion*

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

*Allowable Subject Matter*

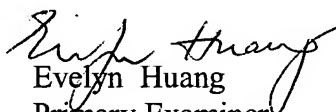
10. Claims 5, 7-9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 18, 19 are allowed. The instant compound with an aryl or heterocyclyl ring as R3, a pyridinylmethyl or pyrimidinylmethyl, thienylmethyl or furanyl as R is not anticipated by the prior art of record. Motivation to modify the prior art of record via multiple changes to arrive at the instant is lacking.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Evelyn Huang  
Primary Examiner  
Art Unit 1625